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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,443	06/02/2005	Andrew I Poutiatine	Dure-038	2643
31498 7590 12/27/2007 DURECT CORPORATION THOMAS P. MCCracken 2 RESULTS WAY CUPERTINO, CA 95014				
EXAMINER HOLLOWAY, IAN KNOBEL				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/537,443

**Applicant(s)**

POUTIATINE ET AL.

**Examiner**

Ian K. Holloway

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 6/02/2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/ISD)
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date 6/2/2005.

## DETAILED ACTION

### ***Claim Objections***

1. Claims 8 are objected to because there are two separate claims designated with the same number. Action needs to be taken in order to revise this problem. For the rest of this application, claim 8, reading: *A catheter feed through guide apparatus of claim 7, wherein said elongated, resilient guide element has a length sufficient such that at least one of said first and second ends extends out of said tunneler when said guide element is positioned within said tunneler.* This claim will be called 8A for the rest of this action. The other claim 8, reading: *A catheter feed through guide apparatus of claim 7, wherein said first end includes a helix having a plurality of coils, said spacing between said coils being sufficient to pass said catheter between adjacent ones of said coils.* This claim will be called 8B for the rest of this action.

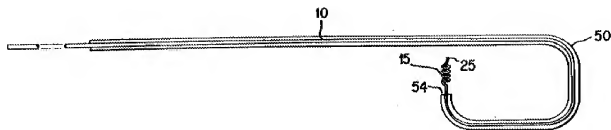
### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by **Chuttani (US Patent 5054501)**.



**FIG. 4**

Regarding **Claim 1**, **Chuttani** discloses a catheter guide apparatus comprising a guide element (Column 6, line 4) configured to fit through a tunneler (Column 6, lines 11-14) and to releasable engage a catheter. (Column 6, line 25-27)

Regarding **Claim 2**, **Chuttani** discloses the catheter guide apparatus of claim 1, wherein said guide element further comprises first (25) and second (14) ends, (Abstract lines 2-3) said first end configured to releasable couple to said catheter (15). (Abstract lines 3-4, the coil is able to perform this task)

Regarding **Claim 3**, **Chuttani** discloses the catheter guide apparatus of claim 2, wherein said guide element has a length sufficient such that at least one of said first and second ends extends out of said tunneler when said guide element is positioned within said tunneler. (Column 6, line 12)

Regarding **Claim 4**, **Chuttani** discloses the catheter guide apparatus of claim 1, wherein said guide element further comprises a helix (15) adjacent one end, (Column 6, line 26) said helix including at least two coils, (Column 6 lines 26-27) said spacing

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between said coils being sufficient to pass said catheter between adjacent ones of said coils.

Regarding **Claim 5, Chuttani** discloses the catheter guide apparatus of claim 4, wherein said helix has an internal diameter which is slightly smaller than an external diameter of said catheter. (Column 6, lines 13-14)

Regarding **Claim 6, Chuttani** discloses the catheter guide apparatus of claim 2, wherein said second end includes a handle. (Column 6, lines 16-17)

Regarding **Claim 7, Chuttani** discloses a catheter feed through guide apparatus comprising an elongated, resilient guide element having first and second ends, (Abstract, lines 2-3) said first end configured to releasably couple to a catheter, (Abstract lines 2-3) said elongated, resilient guide element configured to fit through a tunnel.

Regarding **Claim 8A, Chuttani** discloses a catheter feed through guide apparatus of claim 7, wherein said elongated, resilient guide element has a length sufficient such that at least one of said first and second ends extends out of said tunnel when said guide element is positioned within said tunnel. (Column 6, lines 11-14)

Regarding **Claim 8B, Chuttani** discloses a catheter feed through guide apparatus of claim 7, wherein said first end includes a helix having a plurality of coils, said spacing between said coils being sufficient to pass said catheter between adjacent ones of said coils. (Column 6, lines 26-27, due to the many different sizes of catheters in use, it would be possible to find a catheter that could fit within coils)

Regarding **Claim 9, Chuttani** discloses the catheter feed through guide apparatus of claim 8, wherein said helix has an internal diameter which is slightly smaller than an external diameter of said catheter. (Col 6, lines 13-14)

3. Claims 10-12 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by **Berry (US patent 5306240)**.

Regarding **Claim 10, Berry** discloses the use of a tunneler to place an implantable catheter. It goes through the steps of attaching the catheter to the guide (Column 5, lines 20-22) and passing the guide and catheter through the tunneler. (Column 5, lines 23-26)

Regarding **Claim 11, Berry** discloses the removal of the guide element. (Column 6, lines 3-5)

Regarding **Claim 12, Berry** discloses the steps of attaching the catheter to the guide (Column 5, lines 20-22) and passing the guide and catheter through the tunneler. (Column 5, lines 23-26) it further teaches the removal of the guide element. (Column 6, lines 3-5)

Regarding **Claim 14, Berry** teaches the use of a tunneler to place an implantable catheter. It goes through the steps of attaching the catheter to the guide (Column 5, lines 20-22) and passing the guide and catheter through the tunneler. (Column 5, lines 23-26) it further teaches the removal of the guide element. (Column 6, lines 3-5)

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Berry** in view of **Steiger (US Patent 4453928)**.

Regarding **Claim 13**, **Berry** fails to disclose the steps of inserting the tunneler and removing the tunneler.

**Steiger** teaches the steps of inserting the tunneler (Column 5-6, Lines 26-31 and 1-13) and the removal of the tunneler (Column 6, lines 25-30)

**Berry** discloses the claimed invention except for the steps of inserting and removing the tunneler. **Steiger** teaches that it is known to use a tunneler before attempting to send a catheter through the tunnel. It would have been obvious to one of ordinary skill in the art at the time of the invention was made to utilize a tunneler as taught by **Steiger**, since such modification would make the method more effective.

Thus, it would have been obvious to one of ordinary skill in the art to apply a tunneler as taught in **Steiger**, to improve the guide element of **Berry** for the predictable result of passing a catheter through a tunneler.

***Prior art Cited but not Applied***

**Nichols et al.** discloses the use of a clamp, a fastener, a tie, or any other device that couples in order to attach a guide wire to a catheter. (Page 1, paragraph 11)

**Ruhlman (US Patent 3080631)** discloses a way of wrapping a wire around a linear body in order to provide enough force to bind it and pull it in an axial direction.

**Ross et al. (US Patent 6752827)** teaches the previous use of pulling catheters through tunnelers and how it would have a tendency to damage catheters. (Column 1, Lines 50-51)

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ian K. Holloway whose telephone number is 571-270-3862. The examiner can normally be reached on 8-5, Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrell L. McKinnon can be reached on 571-272-4797. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ian K. Holloway

/Terrell L Mckinnon/  
Supervisory Patent Examiner, Art Unit 4148